

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 14-R-0020

FORM APPROVED
OMB NO. 0579-0036

CUSTOMER NUMBER: 117

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Childrens Hospital The
John Enders Pediatric Research
300 Longwood Avenue Enders 146
Boston, MA 02115

NOV 22 2005

Telephone: (617) ~~355-7038~~ 919-2728

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	52	466	48	566
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	41	0	41
11. Pigs	0	0	122	0	122
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

DATE SIGNED

11/22/05

(b)(6), (b)(7)c

Q99W

NOV 23 2005

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 14-R-0020
2. Number 417 of animals used in this study.
3. Species (common name) rabbits of animals used in this study.
4. Explain the procedure producing pain and/or distress.

The purpose of this study (A04-01-016R, Pedro del Nido, M.D., "Cardiac Hypertrophy and Surgical Ischemia") is to determine the effects of pressure overload hypertrophy induced at birth. There are multiple agents that are then administered in pursuit of evaluation of them in relationship to cardiac hypertrophy.

The study involves anesthetizing the 7-10 day old animals and performing a left thoracotomy. The ductal ligament is then identified and banded. The incision is then closed with prolene sutures and the animals recovered. Analgesics are administered in the immediate postoperative period. Over the course of several weeks the animal will then develop cardiac hypertrophy and receive different drug regimens. At the conclusion of the study they are euthanized and the heart is isolated for histopathological evaluation.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below).

These animals reflect a clinical model of children with a congenital anomaly of the heart and its associated clinical disease. The majority of animals develop secondary signs such as increased respiratory effort and reduced activity gradually and are euthanized prior to significant distress. Our staff has been involved in these studies for over 10 years and have been thoroughly trained in the recognition of early indicators to the moribund state. In these 48 cases the animals developed dramatic clinical disease quickly, which resulted in subsequent heart failure and death. At no time are analgesics or supportive care measures withheld when clinical illness is recognized.

In working with the investigator we have been able to improve our ability to identify early indicators of disease and remove animals from study before significant illness is present. Our goal is to continually reduce this number and hopefully eliminate these situations.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number, and the specific section number (e.g., APHIS, 9 CFR 113.102).

Not applicable.

Agency _____ CFR _____